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CHEN, CATHERYNE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,457

Applicant(s)

BENNETT, BRIAN

Examiner

CATHERYNE CHEN

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-11 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date Oct 2, 2007
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendments filed on Dec. 10, 2007 has been received and entered. Currently, Claims 1-4, 7-11, 18-22 are pending. Claims 1-4, 7-11 are examined on the merits.

The declaration of Exhibit A filed Dec. 10, 2007 has been considered.

Election/Restrictions

Applicant's election of Group I (Claims 1-4, 7-17) in the reply filed on May 29, 2007 is acknowledged.

Response to Arguments

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 7-8, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al. (US 5368844) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no motivation to combine the ingredients and viscosity is not taught, there is synergistic effect.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

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the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Gaffar et al. teaches oral composition on dental surfaces (column 1, lines 24-25) with triclosan (column 2, line 34), comprising a liquid vehicle suitable for topically contact dental surfaces and gums (column 2, lines 51-55), antibacterial agent amount about 0.01 to 5% by weight (column 4, lines 33-35), alexidine (column 5, lines 9-10) at about 0.001 to 15% by weight (column 5, lines 29-30), incorporate preservatives, silicones, flavoring materials (column 13, lines 39-41, 51).

Silicone fluid is intrinsically less than 20 Pascal second. Therefore, the oral composition as taught by the reference as a mouthwash or liquid dentrifice, which is substantially liquid in character (column 12, lines 28-30), is intrinsically less than 20 Pascal second. Furthermore, silicone is intrinsically viscous; thus, all the ingredients are taught.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in

order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

As to Applicant's claim of synergism, the data show 4 out of 10 as suppose to 3 out of 10 having better response with triclosan. The SCORAD show difference 3.844 and 2.618 having better response with triclosan. These data show differences with and without triclosan added; however, it does not show synergistic effect. There is not enough data to compare the data to show there is more than additive effect with triclosan.

Claims 1-4, 7-8, 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littlewood et al. (US 2002/0034478 A1) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the concentration and viscosity are not taught.

Littlewood et al. teaches an oral non-food composition with Triclosan, peppermint extract (paragraph 0002), silicone compound (paragraph 0005), liquid silicone (paragraph 0007), dimethyl polysiloxane with viscosity range of 0.4 to $100 \times 10^{-3} \text{ m}^2 \text{ s}^{-1}$ at 25 degree Celsius (paragraph 0010), dimethyl siloxane having viscosity of 0.05 to $5 \times 100 \times 10^{-3} \text{ m}^2 \text{ s}^{-1}$ (paragraph 0012), alexidine (paragraph 0033), preservatives (paragraph 0044), pharmaceutically acceptable carriers (paragraph 0049), surfactants (paragraph 0050), humectants (paragraph 0052), binder and thickeners (paragraph

0053), 0.001 to 10% by weight of silicone (claim 5). These compositions are viscous and there is viscosity index.

The reference also does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1-4, 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Littlewood et al. (US 2002/0034478 A1) as applied to claims 1-4, 7-8, 10-17 above, and further in view of Schulze zur Wiesche et al. (WO/2001/085106 with US 2003/0206933 A1 as translation) and Hansen et al. (US 5955502) for the reasons set forth in the previous Office Action. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that no triclosan and viscosity are taught.

Littlewood et al. teaches an oral non-food composition with Triclosan, peppermint extract (paragraph 0002), silicone compound (paragraph 0005), liquid silicone (paragraph 0007), dimethyl polysiloxane with viscosity range of 0.4 to $100 \times 10^{-3} \text{m}^2 \text{s}^{-1}$ at 25 degree Celsius (paragraph 0010), dimethyl siloxane having viscosity of 0.05 to $5 \times 100 \times 10^{-3} \text{m}^2 \text{s}^{-1}$ (paragraph 0012), alexidine (paragraph 0033), preservatives (paragraph 0044), pharmaceutically acceptable carriers (paragraph 0049), surfactants (paragraph 0050), humectants (paragraph 0052), binder and thickeners (paragraph 0053), 0.001 to 10% by weight of silicone (claim 5).

Schulze zur Wiesche et al. teaches agent for skin (paragraph 0003), in liquid form in aqueous dispersion (paragraph 0203), jojoba oil (paragraph 0208), liquid paraffin oils (paragraph 0209), stearic acid (paragraph 0210), aloe vera (paragraph 0234), silicones (paragraph 0251), Carbomer (paragraph 0321), NIPA (paragraph 0356).

Hansen et al. teaches agent for skin or mucosa (column 1, lines 9-11) with 1,2-propanediol (column 5, line 8), glyceryl monostearate, water (column 6, lines 20-21, 45), triethanolamine (column 15, line 13), castor oil (column 15, line 20), cetyl palmitate (column 15, lines 31-32).

The references also do not specifically teach formulating the composition in the forms claimed by applicant. These pharmaceutical forms are well known in the art to be fatty substances that can be used to make aqueous dispersions due to their bioadhesive properties to make paste or gel formulations (Schulze zur Wiesche et al. paragraph 0203; Hansen et al. column 4, line 44; Littlewood et al. paragraph 0057).

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Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulating the composition taught by the reference in the forms claimed by applicant.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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